SURGICAL MANUAL

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Lospa

KNEE SYSTEM

IMPLANT SPECIALIST

Table of Contents

I. Surgical Preparation

Introduction

The Lospa Knee System offers anatomically featured shape for both a cruciate retaining (CR) to a posterior stabilized(PS) knee within a single system, to reproduce patients more natural knee motion and increase the implant longevity.

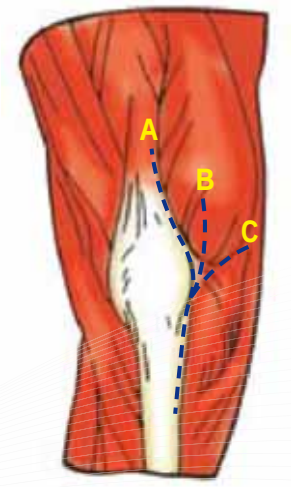
Each surgeon is responsible for determining the appropriate device and technique to utilize on each individual patient. Lospa Instrumentation is designed to address patient variables and individual surgeon preferences. This surgical protocol depicts femoral preparation first, followed by tibial preparation. This order may be changed to address patient indications or surgeon's preference.

Preoperative Planning

The angle between the anatomic axis (center of the knee-intramedullary canal) and the mechanical axis (Center of the femoral head-center of the knee) defines the valgus angle.

These angles should be determined for both knees. This angle must be determined before performing the distal femoral resection by comparison with the healthy joint in order to restore this valgus angle in the diseased joint.

Femoral component size is estimated preoperatively by using lateral view X-rays and radiographic templates. Lateral view templates are used to approximate the appropriate A/P size component is confirmed intraoperatively. Standard magnification is 110%.



A- Medial Parapatellar
B- Mid Vastus
C- Sub Vastus

Approaches

Lospa Knee Instruments are designed for use of three basic procedures: Medial Parapatellar, Mid-vastus, and Sub-vastus surgical techinique.

The medial parapatellar approach can begin at the top medial corner of the patella and continuing down along the patellar tendon, ending at the patellar tendon insertion.

The mid-vastus approach can create extensive exposure without violating the quadriceps tendon with only a small split in the vastus medialis obliques muscle.

The sub-vastus approach preserves the quadriceps muscle and tendon, but requires careful assessment of patellar mobility as well as size and bulk of the quadriceps muscle mass.

II. Femoral Preparation

Distal Femoral Resection

Starter Hole Preparation: Begin with Starter Awl.

Intramedullary twist drill should be used to drill a hole in the distal femur coaxial with the femoral endosteal canal. It is 1cm anterior to the femoral attachment of the posterior cruciate ligament and slightly medial to the midline for the distal femur. *(Figure 1-2)*

Attach the T-Handle Driver to the Femoral IM Rod. After opening the canal with the twist drill, Femoral IM Rod should be inserted into the femoral canal to be sure that it passes easily. *(Figure 3)*

Set the adjustable Distal Cutting Jig to the desired valgus angle by pressing it. A Valgus Guide angle setting of 3 to 9 degrees is available. (The standard distal cutting is 9mm, matching the distal thickness .) *(Figure 4-5)*

Figure 1

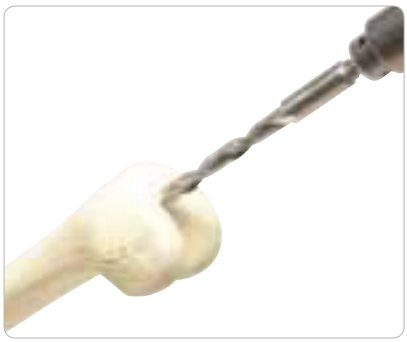


Figure 2

Figure 3

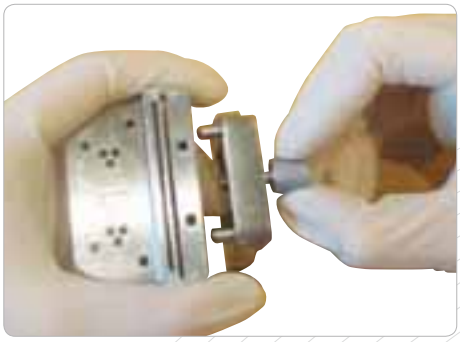


Figure 4

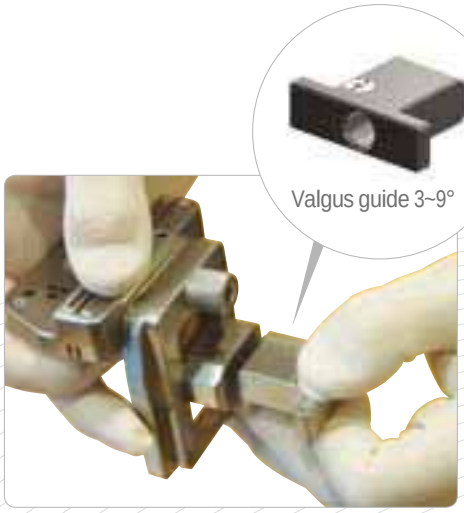


Figure 5

Prior to pinning the Distal Cutting Guide to the femur, an optional EM alignment tower may be performed. Attach the EM Alignment Tower to the Distal Cutting Guide and insert an external EM Alignment Rod into the tower. Alignment is correct when the rod intersects the center of the femoral head and roughly parallels the axis of the femur in the lateral view. *(Figure 6)*

The Distal Cutting Guide Tower is connected to the alignment instrument for valgus angle. Two resection slots of 0mm or +3mm are available for distal resection. The 0mm slot will resect 9mm from the distal condyle, the 3mm slot will resects 12mm.(3mm more than the thickness)

Pin the Distal Cutting Guide to the anterior femur using pins, the preferred initial position for the pins is in the holes marked “0” position on the Distal Cutting Guide. (±2mm avaliable) Remove the EM Alignment Rod after the Distal Cutting Guide is pinned in place. *(Figure 7)*

Once the final resection level is determined, the distal femoral resection is made. Make the distal resection using an 1.20mm thick oscillating saw blade. Remove the distal cutting guide and check the resection for flatness. *(Figure 8)*

Figure 6

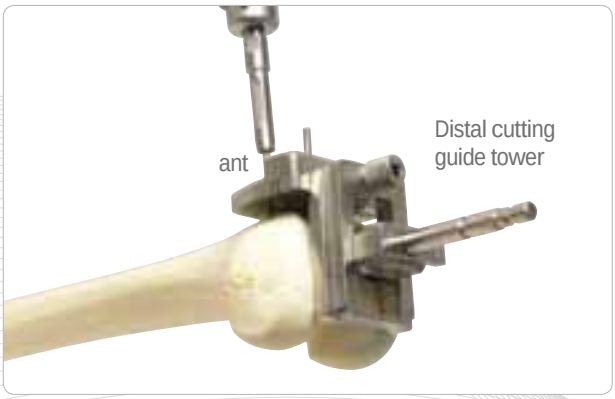


Figure 7

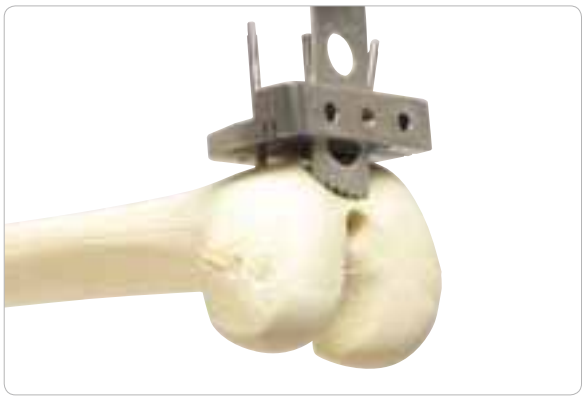


Figure 8

II. Femoral Preparation

Femoral Sizing

Attach the external rotation guide to AP sizer. The External Rotation Guide is available 0, 3, 4, 5 degree. *(Figure 1)*

Place the A/P Sizer flat against the resected distal surface with the feet in contact with posterior condyles of the femur. M/L width checker can be inserted into the A/P Sizer to further evaluate the proper size of the femur. *(Figure 2)*

The size is indicated on the gauge on the front of the A/P Sizer, if the indicator is midway between sizes, the smaller size should be chosen. The medial/lateral sizing wings should be deployed to check the femoral width.

Check Anterior Resection

Angel wing gauge may be inserted in the numbered slot on the side of the A/P Sizer. Angel Wing can be used to determine the amount of anterior bone resection. *(Figure 3)*

Pinning the A/P sizer to put the Chamfer Cutting Guide. Drill the external rotational hole. The Posterior Condylar Axis is determined *(Figure 4)*

*External rotation guide: reversible (Indicated Left & Right side: distinguished from front/back side)

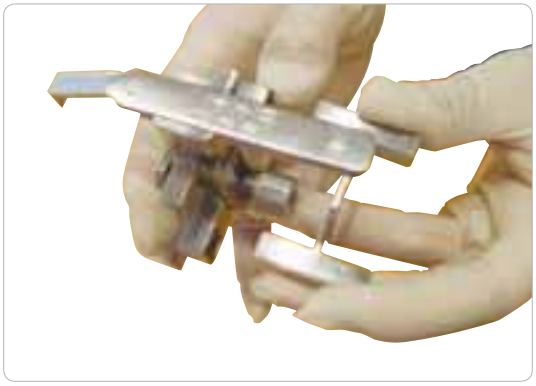


Figure 1

Figure 2

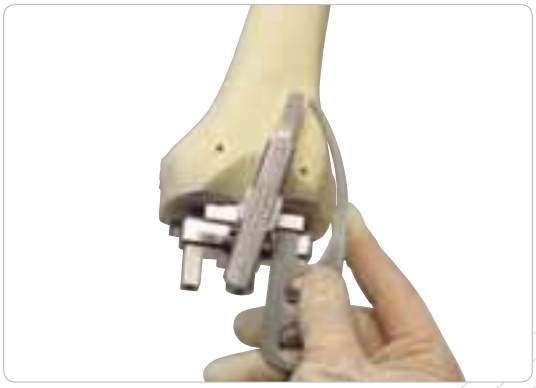


Figure 3

Figure 4

Femoral (A/P) Chamfer Cutting Guide

It remains same anterior cutting location regardless using the different size of Chamfer Cutting Guide. *(Figure 1)*

The Femoral Redriller can be used to shift the Chamfer Cutting Guide holes anteriorly in one millimeter increments up and down, if the Angel Wing indicates a probability of a notch occurring. Position the femoral Chamfer Cutting Guide on the distal femur. The anterior lip of the block should sit flush against the resected anterior femur. Using the pin driver and a mallet, drive the two pins into the femur. *(Figure 1-1)*

Complete the remaining four femoral bone resections.
(Anterior Condyle ▸ Posterior Condyle ▸ Anterior Chamfer ▸ Posterior Chamfer) *(Figure 2)*

After the femur has been cut, remove the chamfer cutting guide by inserting the removal pin on the slide hammer into the extraction hole by using the pin extractor to pull the guide off distal femur.

Check the flexion/extension .

Figure 1

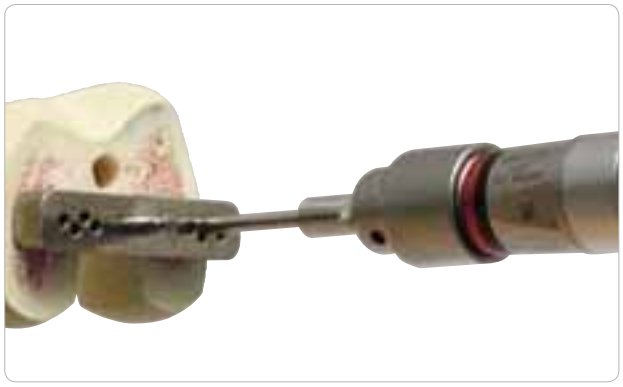


Figure 1-1

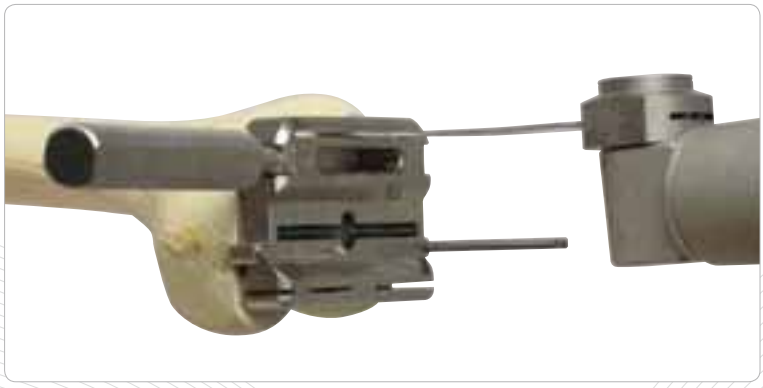


Figure 2

II. Femoral Preparation

PS Box Preparation

PS/CR Box Cutting Jig has the same shape of real implant.

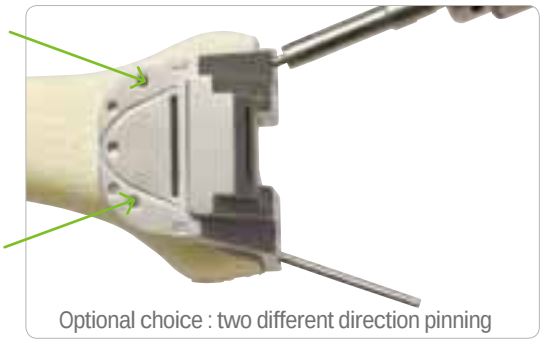
Impact the size specific PS Box Cutting Jig on the prepared distal femur. The PS Box Cutting Jig is fixed with no fewer than two and up to three pins. *(Figure 1)*

Impact the chisel to a depth one-half the thickness of the femur. *(Figure 2)*

Resect along the interior of the PS Box Cutting Jig with an oscillating saw. Continue both cuts from the anterior portion through to the posterior. Finish impacting the box chisel until the intercondylar bone is removed and to make intercondylar cam design. Care should be taken to visualize posterior soft tissue structures, which should be retracted from the path of the chisel. *(Figure 3)*

CR Type : Impact the chisel to a depth one half the thickness of the femur. Before the trochlea is resected with the chisel for patellar intercondylar groove, the PS Box Cutting Jig is aligned a little lateral of center. Then the trochlea is resected with the chisel. Different anterior chamfer cutting location. *(Figure 4)*

*Option : prepare peg drill after PS Box Preparation or after Femoral trial stage based on the Surgeon's preference



Optional choice : two different direction pinning

Figure 1

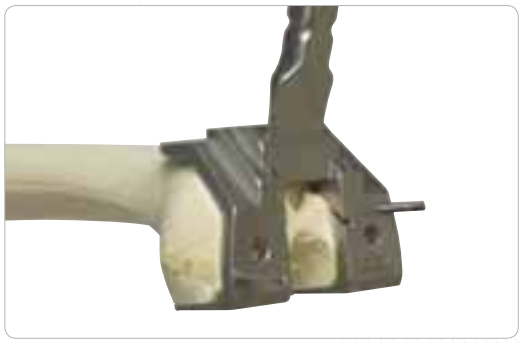


Figure 2

Figure 3

CR Type : notch chisel

Figure 4

III. Tibial Preparation

Tibial Resection

Extramedullary Tibial Resection

With the knee flexed, place the spring-loaded ankle clamp around the distal tibia just above the malleoli. The EM Tibial Cutting Guide should be placed on the anterior tibia. Center over the ankle joint. In the sagittal plane, the EM Tibial Cutting Guide should be aligned parallel to a line extending from the center of the knee joint to the center of the ankle joint. Centering the shaft of the EM Tibial Cutting Guide on the center of the tibial plateau will provide correct medial/lateral alignment of the Tibial Cutting Guide. To establish the posterior slope, the shaft of the EM Tibial Cutting Guide should be adjusted so that it is parallel to the long axis of the tibia in the anterior/posterior plane. *(Figure 1)*

The tibial Stylus is attached to the Tibial Cutting Guide. The Stylus has two tips representing 0 and 10mm resection measurements for the depth. *(Figure 2)*

The angel wing may be placed through the cutting slot on the Tibial Cutting Guide to aid in establishing the position parallel to the surface of the tibial plateau. *(Figure 3)*

The resector head is locked into place by tightening the EM Tibial Cutting Guide. Starting with the most lateral hole, pin the resector head with 1/8"headless pins in the most distal holes. *(Figure 4)*

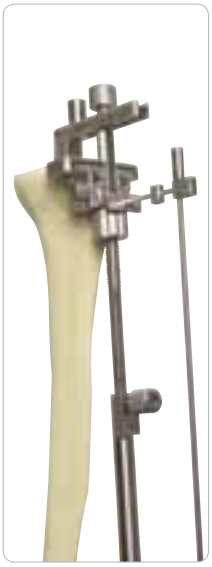
Then, remove the Tibial Cutting Guide. *(Figure 5)*

*Tibial Cutting Guide (Size available 0,3,5 degree) and Separated Left / Right side instrument available

Figure 1

Figure 2

Figure 3



Tibial Axis Check

Figure 4

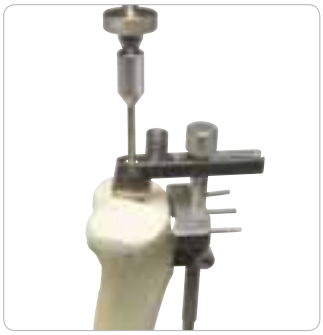


Figure 5

Intramedullary Tibial Resection

The Twist Drill is used to create a hole in the proximal tibia. Insert T-Handle Rod : IM rod should pass easily into the canal. *(Figure 1)*

Attach the Tibial Cutting Guide to the shaft of the Tibial Cutting Guide. The alignment IM rod should be aligned with the second toe. The tibial Stylus is attached to the Tibial Cutting Guide. Once the final position of the Tibial Cutting Guide is established, drill pins are used to fix the position of the guide. *(Figure 2)*

Proximal Tibia Cutting: The proximal tibia is resected using a (1.20mm) oscillating saw blade placed through the cutting slots of the guide. After performing the resection, the angel wing may be used to assure that the resected surface of the tibia is flat. *(Figure 3)*

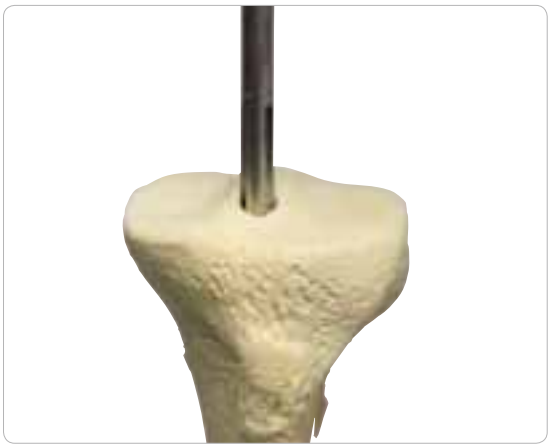


Figure 1

Figure 2

Figure 3

IV. Tibial Sizing

The resected tibial surface is sized using the tibial tray trials. The Surgeon should used the largest tibial tray that fits within the borders of the resected tibial surface without any overhang. The tibial trial is placed after confirm axis, and pinned using the provided headed pins. *(Figure 1)*

Tibial Keel Punch

With the tibial tray trial firmly pinned in its final position, the Tibial Keel Punch is used to create the cavity for the tibial component keel. Care must be taken to used the correct size punch for the selected size of tibial component. (Three Punches are provided, sizes S, M, and L / S-#3, M-#4, 5, 7, 9, L-#11) *(Figure 2-3)*

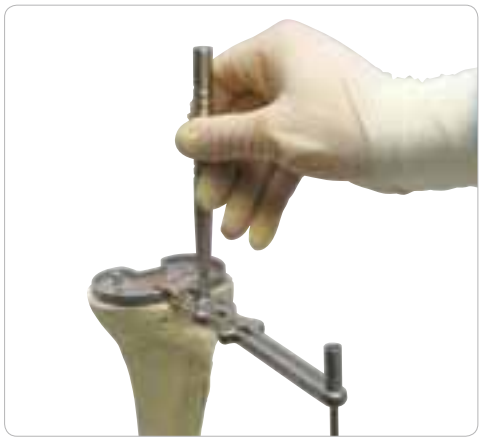


Figure 1

Figure 2

Figure 3

V. Patellar Preparation

Patellar Sizing

Patellar thickness is measured using the patellar caliper. An estimate of the patellar diameter can be obtained by using the patellar sizing guide. Patellar diameters of 26, 28,32, 34, 36 are available. *(Figure 1)*

Patellar Resection

Patellar Resection Guide provides accurate, repeatable measurement of patellar resection. As the patellar is clamped in the jaws of the resection guide, the amount of resection is read. (Remaining patellar thickness after cutting)

The Patellar clamp saw capture slots accommodate a (1.20mm) saw blade. *(Figure 2-3)*

Peg Holes Drill

The holes for the 3pegs on the patellar are prepared using the patellar clamp with Peg Drill Guide loaded. *(Figure 4-5)*

The patellar surface and the back of the patellar component should be coated with cement. The patellar clamp is then used to compress the patellar component firmly onto the patellar. Excess cement should be removed.

Figure 1

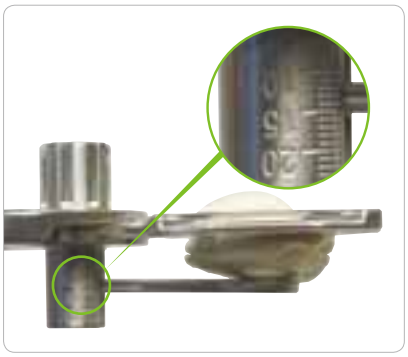


Figure 2

Figure 3

Figure 4

Figure 5

VI. Trial Reduction

Femoral Implant Insertion

Implant the appropriate tibial component, bearing and femoral component, using cement, in the same order and manner as the trials. Cement is to be used, a layer of cement should be applied to the resected surface of the distal femur and to the back of the femoral component.

Femoral Trial Insertion

Femoral Preparation

Attach the femoral extractor to the appropriate size and side femoral component.
The femoral impactor can be used to further seat the femoral component onto the prepared femur. *(Figure 1-3)*

Prepare Peg Drilling

Attach the Peg Drill to the Universal Driver and create the modular femoral distal fixation Peg holes. *(Figure 4)*

Figure 1

Figure 2

Figure 3

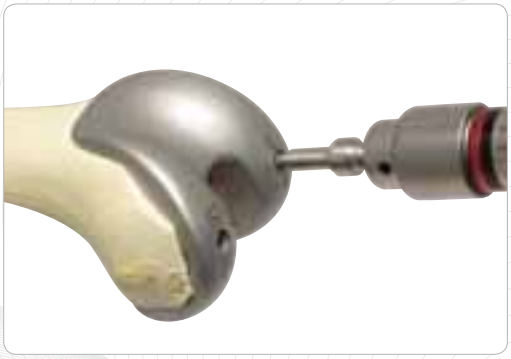


Figure 4

VI. Trial Reduction

Tibial Implant Insertion

Impacting the real implant by using the Insert Impactor. Rest of procedures is the same order and manner as the trials. *(Figure 5)*

Tibial Trial Insertion

Insertion Tibial Baseplate

The cement should be mixed and placed on the cut surface of the proximal tibia by hand. Cement should be applied to the back of the tibial tray and the tibial tray should be placed and impacted using the tibial impactor.

Connect the Tibial Baseplate Driver to the primary tibial baseplate.

Introduce the primary tibial baseplate onto the prepared tibia and impact until the baseplate is seated with the Tibial Baseplate Impactor.

Unlock the locking lever and remove the assembly from the primary tibial baseplate. *(Figure 1-2)*

PS or CR Tibial Insert

The surface of the tibial tray should be meticulously cleaned prior to placement of the tibial insert.

Impact to snap the insert in place anteriorly with the Tibial Insert Impactor . The PS or CR tibial insert is fully seated once the locking hooks locks on the anterior/interior surface of the primary tibial baseplate wall. *(Figure 3)*

Trial Axis Check

Should make a final check for correct alignment by securing the tibial alignment. The alignment rod is placed through the slot in the alignment handle, and the alignment rod should lie proximal to the tibia plateau. The distal tip of the alignment rod should lie over the center of the ankle. *(Figure 4)*

Figure 1

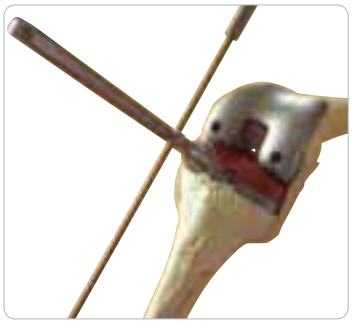


Figure 2

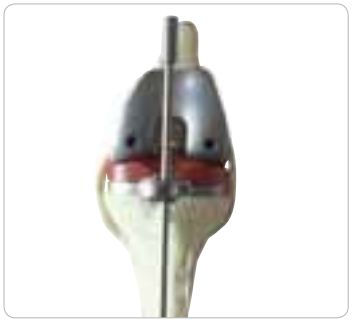


Figure 3

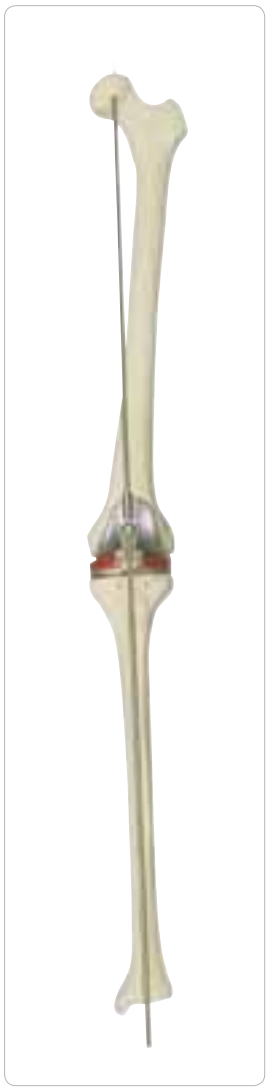


Figure 4

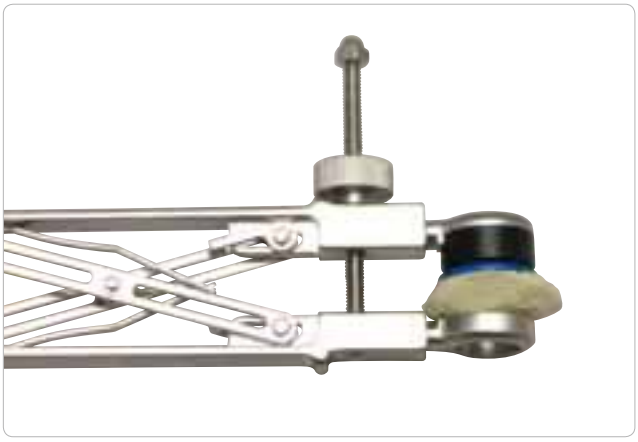
Figure 5
Tibial Implant Insertion

Patellar Trial Insertion

Place the appropriate patellar component into the patella and push it into position with finger pressure so the peg engage the prepared hole.

Position the patellar clamp onto the component and tighten the handle until the clamp head contacts the component. Clamp tightly to compress the implant.

Remove extruded cement with a curette.



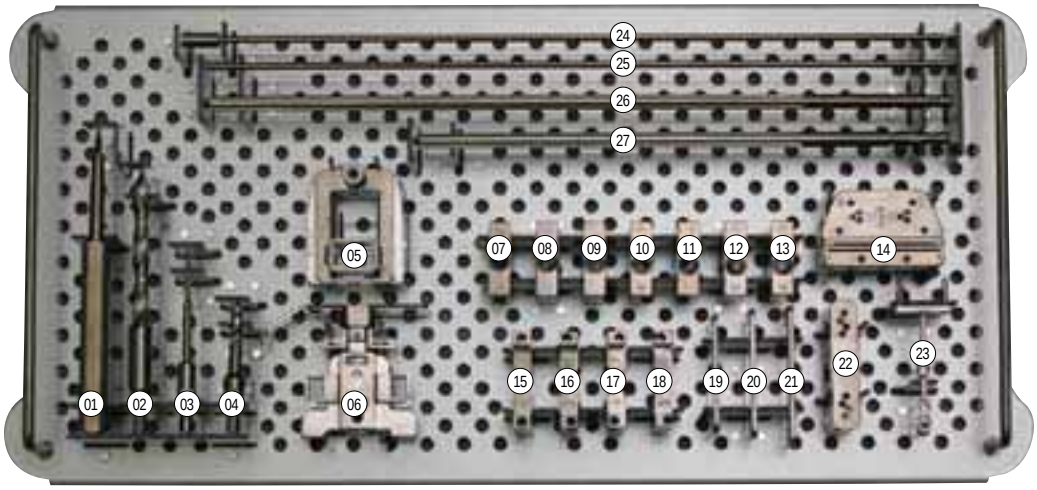
VII. Size Combination Chart

Fixed bearing couple

Tibial inserts	Femoral components					
	F3 (R20) 51AP / 59ML	F4 (R21) 54AP / 62ML	F5 (R22) 57AP / 65ML	F7 (R23) 60AP / 68ML	F9 (R24) 63AP / 71ML	F11 (R25) 66AP / 74ML
T3 (R21.5) 40AP / 61ML	•					
T4 (R22.5) 42AP / 64ML		•				
T5 (R23.5) 44AP / 67ML			•			
T7 (R24.5) 46AP / 72ML				•		
T9 (R25.5) 48AP / 74ML					•	
T11 (R26.5) 50AP / 76ML						•

Size Combination Chart : Fixed type

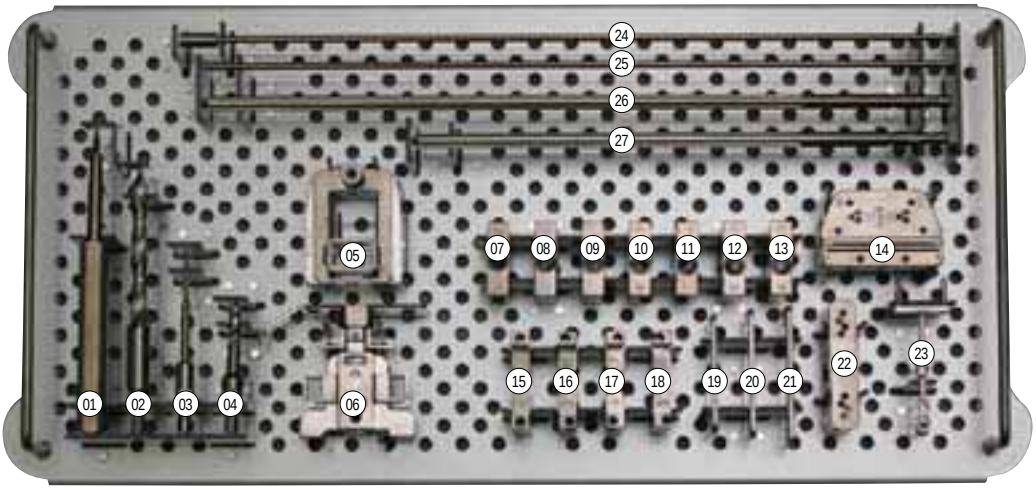
Ⅷ. Instrument Ordering Information



Femur Top Tray

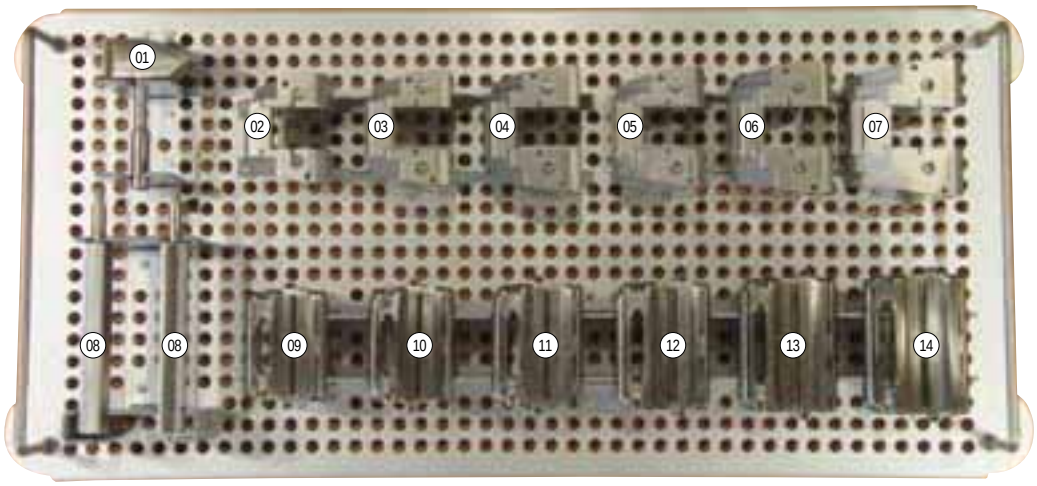
Label No.	Part No.	Description	Product
01	01.61.110	Starter awl	
02	01.61.111	Twist drill	
03	01.61.217	Guide drill	
04	01.61.154	Femoral condyle drill	
05	01.61.123	Distal cutting guide tower	
06	01.61.126	AP sizer	
07	01.61.113	Valgus guide - 3°	
08	01.61.114	Valgus guide - 4°	
09	01.61.115	Valgus guide - 5°	
10	01.61.116	Valgus guide - 6°	
11	01.61.117	Valgus guide - 7°	
12	01.61.118	Valgus guide - 8°	
13	01.61.119	Valgus guide - 9°	

Ⅷ. Instrument Ordering Information



Femur Top Tray

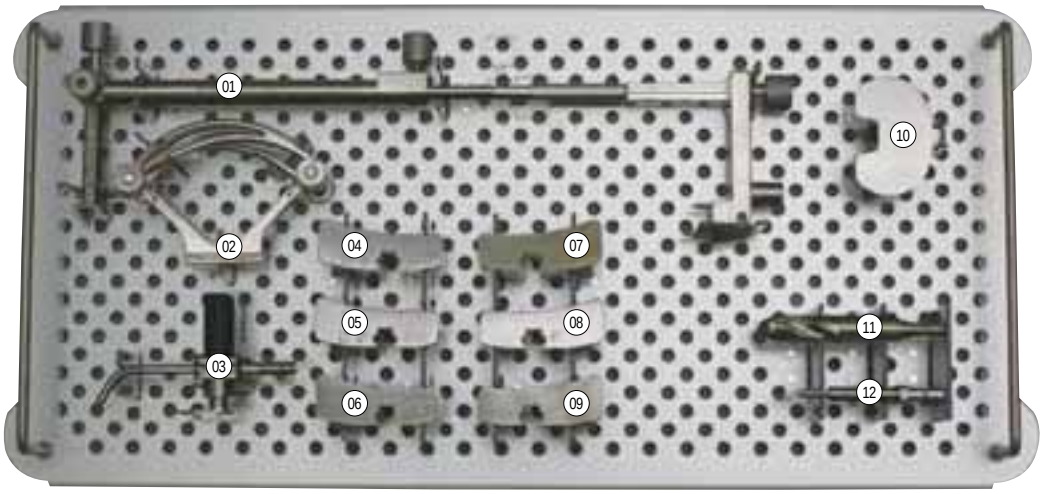
Label No.	Part No.	Description	Product
14	01.61.124	Distal cutting guide	
15	01.61.126-0503	External Rotation Guide - 0°	
16	01.61.126-0503	External Rotation Guide - 3°	
17	01.61.126-0503	External Rotation Guide - 4°	
18	01.61.126-0503	External Rotation Guide - 5°	
19	01.61.230	ML size cracker 3/4	
20	01.61.231	ML size cracker 5/7	
21	01.61.232	ML size cracker 9/11	
22	01.61.153	Femoral Redriller	
23	01.61.122	EM alignment tower	
24	01.61.120	EM alignment rod 400mm	
25	01.61.121	EM alignment rod 400mm	
26	01.61.112-01	Femoral IM rod - 286mm	
27	01.61.112-02	Femoral IM rod - 400mm	



Femur Bottom Tray

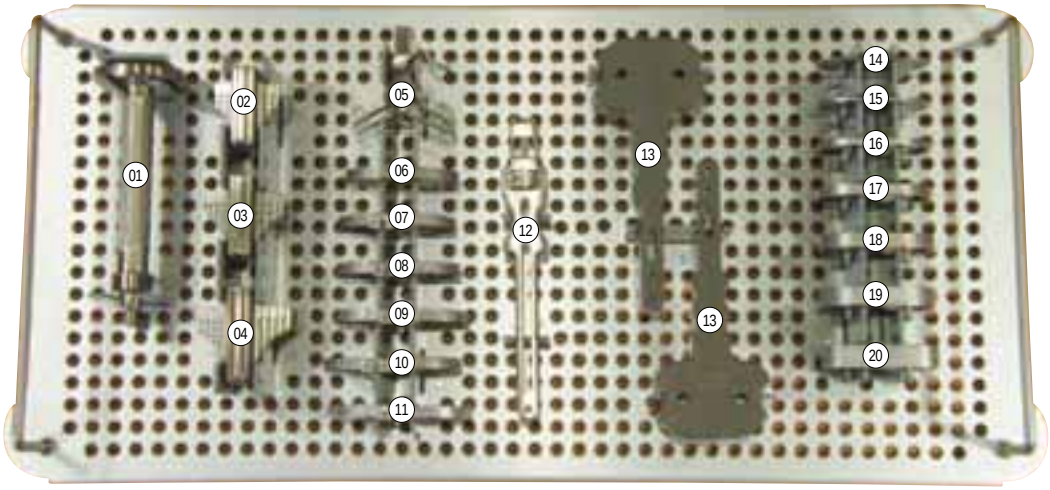
Label No.	Part No.	Description	Product
01	01.61.150	PS box gage	
02	01.61.143	PS box cutting guide SZ3	
03	01.61.144	PS box cutting guide SZ4	
04	01.61.145	PS box cutting guide SZ5	
05	01.61.147	PS box cutting guide SZ7	
06	01.61.149	PS box cutting guide SZ9	
07	01.61.14B	PS box cutting guide SZ11	
08	01.61.213	Removable handle	
09	01.61.133	Chamfer cutting guide SZ3	
10	01.61.134	Chamfer cutting guide SZ4	
11	01.61.135	Chamfer cutting guide SZ5	
12	01.61.137	Chamfer cutting guide SZ7	
13	01.61.139	Chamfer cutting guide SZ9	
14	01.61.13B	Chamfer cutting guide SZ11	

Ⅷ. Instrument Ordering Information



Tibial Top Tray

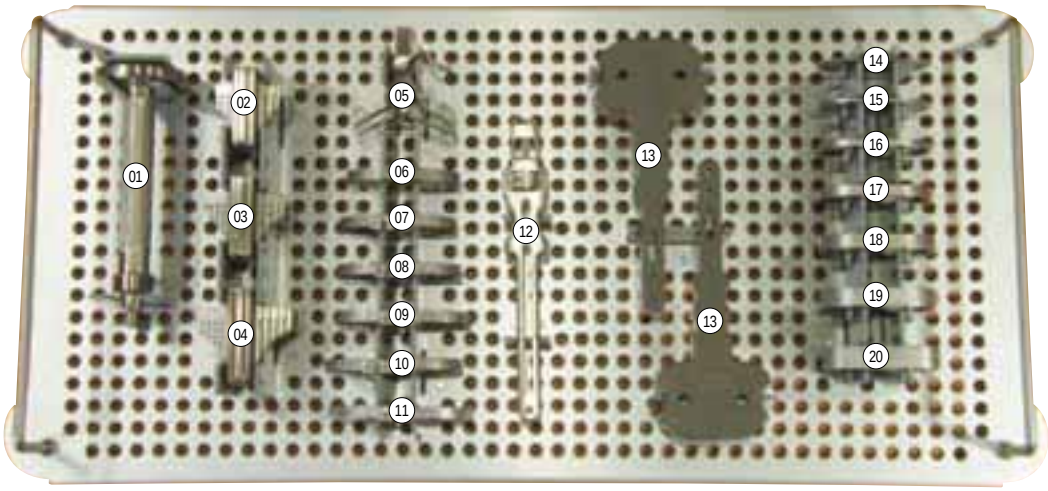
Label No.	Part No.	Description	Product
01	01.61.171	Tibial telescopic assy	
02	01.61.172	Ankle clamp	
03	01.61.179	Tibial stylus	
04	01.61.173	Tibial cutting guide - LT 0°	
05	01.61.174	Tibial cutting guide - LT 3°	
06	01.61.175	Tibial cutting guide - LT 5°	
07	01.61.176	Tibial cutting guide - RT 0°	
08	01.61.177	Tibial cutting guide - RT 3°	
09	01.61.178	Tibial cutting guide - RT 5°	
10	01.61.227	Tibial protector	
11	01.61.181	Tibial drill	
12	01.61.186	Tibial keel reamer	



Tibial Bottom Tray

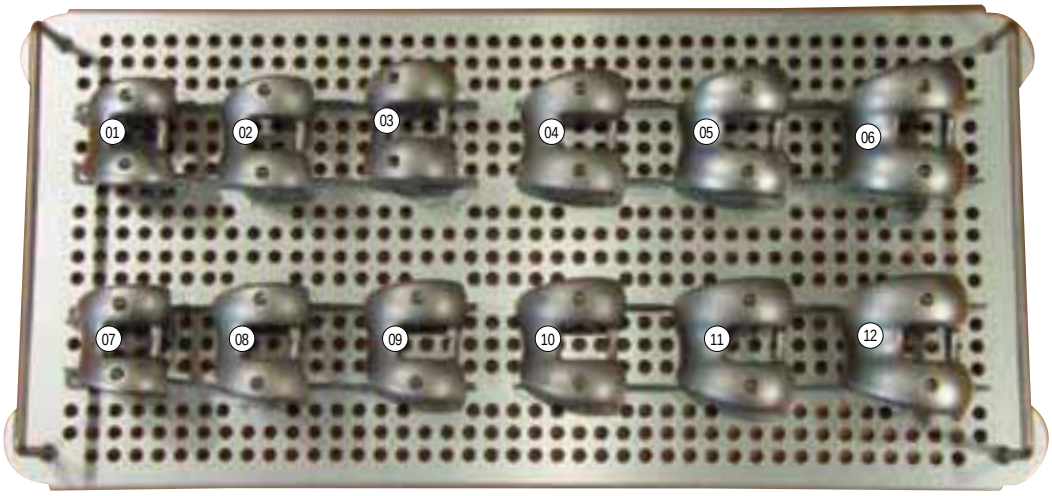
Label No.	Part No.	Description	Product
01	01.61.229	Tibial keel punch impactor	
02	01.61.183	Tibial keel punch - S	
03	01.61.184	Tibial keel punch - M	
04	01.61.185	Tibial keel punch - L	
05	01.61.182	Tibial keel punch guide	
06	01.62.503	Tibial baseplate trial-Fixed-SZ 3	
07	01.62.504	Tibial baseplate trial-Fixed-SZ 4	
08	01.62.505	Tibial baseplate trial-Fixed-SZ 5	
09	01.62.507	Tibial baseplate trial-Fixed-SZ 7	
10	01.62.508	Tibial baseplate trial-Fixed-SZ 9	
11	01.62.509	Tibial baseplate trial-Fixed-SZ 11	

Ⅷ. Instrument Ordering Information



Tibial Bottom Tray

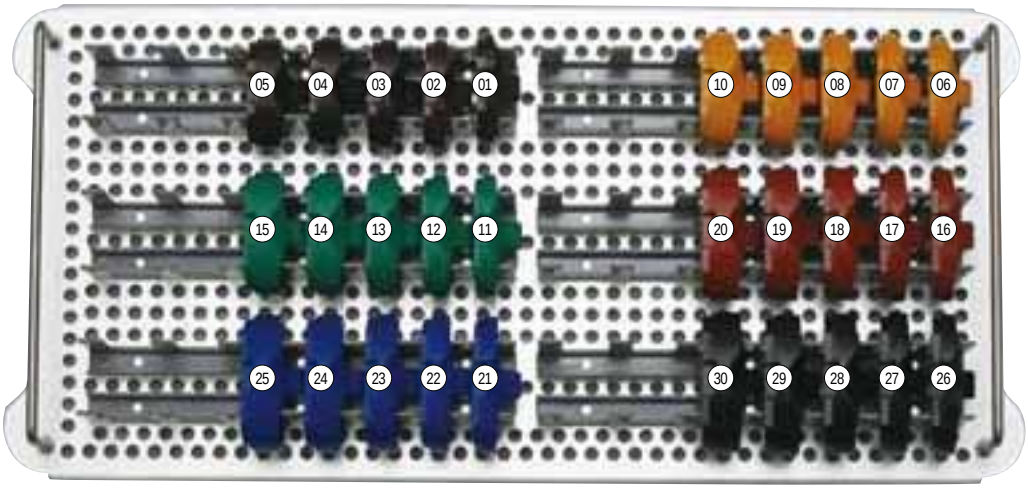
Label No.	Part No.	Description	Product
12	01.61.180	Baseplate handle	
13	01.61.190	Gap gage handle	
13	01.61.190	Gap gage handle	
14	01.61.191-00	Gap gage insert for flexion	
15	01.61.191-02	Gap gage insert 10mm	
16	01.61.191-04	Gap gage insert 12mm	
17	01.61.191-06	Gap gage insert 14mm	
18	01.61.191-08	Gap gage insert 16mm	
19	01.61.191-10	Gap gage insert 18mm	
20	01.61.191-12	Gap gage insert 20mm	



Femoral Trial Tray

Label No.	Part No.	Description	Product
01	01.62.04D	Femoral trial-PS-SZ 3, Right	
02	01.62.063	Femoral trial-PS-SZ 4, Right	
03	01.62.064	Femoral trial-PS-SZ 5, Right	
04	01.62.065	Femoral trial-PS-SZ 7, Right	
05	01.62.067	Femoral trial-PS-SZ 9, Right	
06	01.62.069	Femoral trial-PS-SZ 11, Right	
07	01.62.043	Femoral trial-PS-SZ 3, Left	
08	01.62.044	Femoral trial-PS-SZ 4, Left	
09	01.62.045	Femoral trial-PS-SZ 5, Left	
10	01.62.047	Femoral trial-PS-SZ 7, Left	
11	01.62.049	Femoral trial-PS-SZ 9, Left	
12	01.62.04B	Femoral trial-PS-SZ 11, Left	

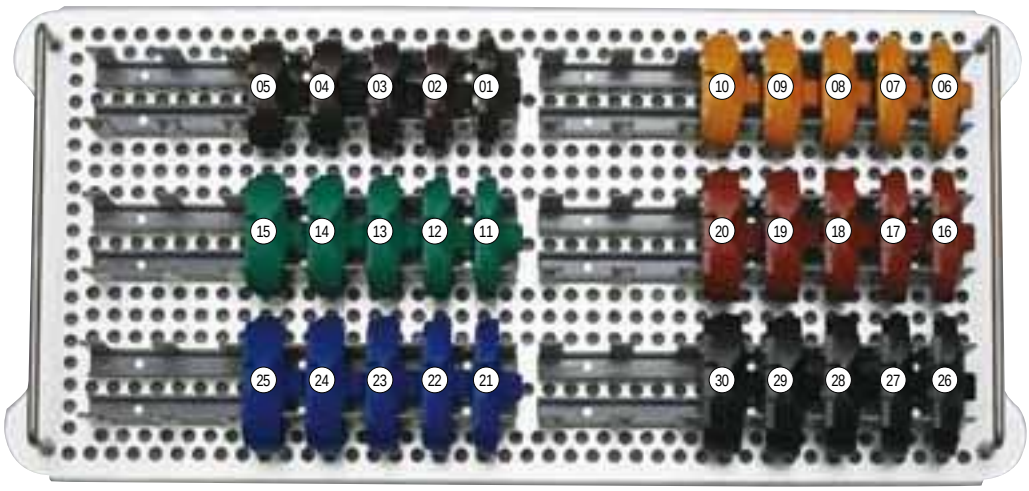
Ⅷ. Instrument Ordering Information



Tibial Insert Trial-Fixed(PS Type) Tray

Label No.	Part No.	Description	Product
	01.62.230	Tibial insert trial-Fixed-PS-SZ 3-8T	
01	01.62.232	Tibial insert trial-Fixed-PS-SZ 3-10T*	
02	01.62.234	Tibial insert trial-Fixed-PS-SZ 3-12T*	
03	01.62.236	Tibial insert trial-Fixed-PS-SZ 3-14T*	
04	01.62.238	Tibial insert trial-Fixed-PS-SZ 3-16T*	
05	01.62.23A	Tibial insert trial-Fixed-PS-SZ 3-18T*	
	01.62.23C	Tibial insert trial-Fixed-PS-SZ 3-20T	
	01.62.23E	Tibial insert trial-Fixed-PS-SZ 3-22T	
	01.62.23G	Tibial insert trial-Fixed-PS-SZ 3-24T	
	01.62.23I	Tibial insert trial-Fixed-PS-SZ 3-26T	
	01.62.240	Tibial insert trial-Fixed-PS-SZ 4-8T	
06	01.62.242	Tibial insert trial-Fixed-PS-SZ 4-10T*	
07	01.62.244	Tibial insert trial-Fixed-PS-SZ 4-12T*	
08	01.62.246	Tibial insert trial-Fixed-PS-SZ 4-14T*	
09	01.62.248	Tibial insert trial-Fixed-PS-SZ 4-16T*	
10	01.62.24A	Tibial insert trial-Fixed-PS-SZ 4-18T*	
	01.62.24C	Tibial insert trial-Fixed-PS-SZ 4-20T	
	01.62.24E	Tibial insert trial-Fixed-PS-SZ 4-22T	
	01.62.24G	Tibial insert trial-Fixed-PS-SZ 4-24T	
	01.62.24I	Tibial insert trial-Fixed-PS-SZ 4-26T	
	01.62.250	Tibial insert trial-Fixed-PS-SZ 5-8T	
11	01.62.252	Tibial insert trial-Fixed-PS-SZ 5-10T*	
12	01.62.254	Tibial insert trial-Fixed-PS-SZ 5-12T*	
13	01.62.256	Tibial insert trial-Fixed-PS-SZ 5-14T*	
14	01.62.258	Tibial insert trial-Fixed-PS-SZ 5-16T*	
15	01.62.25A	Tibial insert trial-Fixed-PS-SZ 5-18T*	
	01.62.25C	Tibial insert trial-Fixed-PS-SZ 5-20T	
	01.62.25E	Tibial insert trial-Fixed-PS-SZ 5-22T	
	01.62.25G	Tibial insert trial-Fixed-PS-SZ 5-24T	
	01.62.25I	Tibial insert trial-Fixed-PS-SZ 5-26T	

* : Flow production

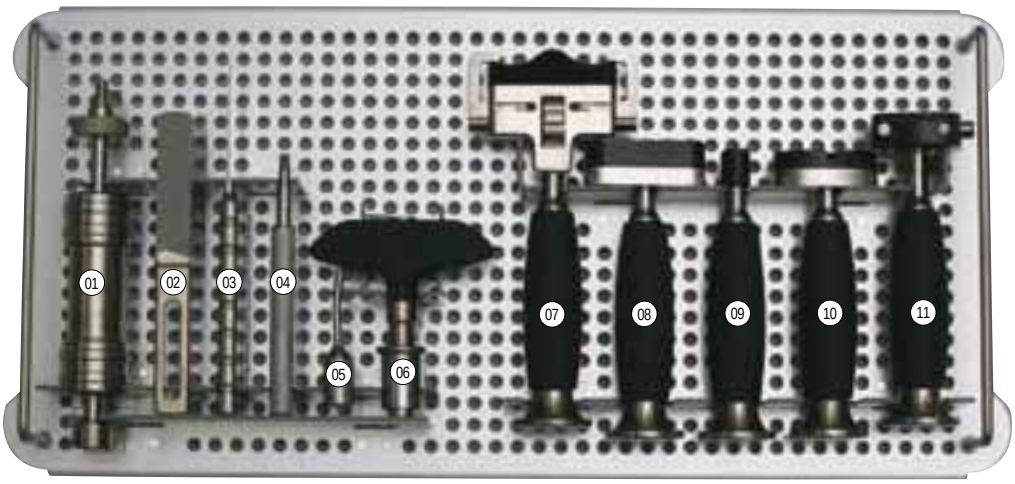


Tibial Insert Trial-Fixed(PS Type) Tray

Label No.	Part No.	Description	Product
	01.62.270	Tibial insert trial-Fixed-PS-SZ 7-8T	
16	01.62.272	Tibial insert trial-Fixed-PS-SZ 7-10T*	
17	01.62.274	Tibial insert trial-Fixed-PS-SZ 7-12T*	
18	01.62.276	Tibial insert trial-Fixed-PS-SZ 7-14T*	
19	01.62.278	Tibial insert trial-Fixed-PS-SZ 7-16T*	
20	01.62.27A	Tibial insert trial-Fixed-PS-SZ 7-18T*	
	01.62.27C	Tibial insert trial-Fixed-PS-SZ 7-20T	
	01.62.27E	Tibial insert trial-Fixed-PS-SZ 7-22T	
	01.62.27G	Tibial insert trial-Fixed-PS-SZ 7-24T	
	01.62.27I	Tibial insert trial-Fixed-PS-SZ 7-26T	
	01.62.280	Tibial insert trial-Fixed-PS-SZ 9-8T	
21	01.62.282	Tibial insert trial-Fixed-PS-SZ 9-10T*	
22	01.62.284	Tibial insert trial-Fixed-PS-SZ 9-12T*	
23	01.62.286	Tibial insert trial-Fixed-PS-SZ 9-14T*	
24	01.62.288	Tibial insert trial-Fixed-PS-SZ 9-16T*	
25	01.62.28A	Tibial insert trial-Fixed-PS-SZ 9-18T*	
	01.62.28C	Tibial insert trial-Fixed-PS-SZ 9-20T	
	01.62.28E	Tibial insert trial-Fixed-PS-SZ 9-22T	
	01.62.28G	Tibial insert trial-Fixed-PS-SZ 9-24T	
	01.62.28I	Tibial insert trial-Fixed-PS-SZ 9-26T	
	01.62.290	Tibial insert trial-Fixed-PS-SZ 9-8T	
26	01.62.292	Tibial insert trial-Fixed-PS-SZ 11-10T*	
27	01.62.294	Tibial insert trial-Fixed-PS-SZ 11-12T*	
28	01.62.296	Tibial insert trial-Fixed-PS-SZ 11-14T*	
29	01.62.298	Tibial insert trial-Fixed-PS-SZ 11-16T*	
30	01.62.29A	Tibial insert trial-Fixed-PS-SZ 11-18T*	
	01.62.29C	Tibial insert trial-Fixed-PS-SZ 11-20T	
	01.62.29E	Tibial insert trial-Fixed-PS-SZ 11-22T	
	01.62.29G	Tibial insert trial-Fixed-PS-SZ 11-24T	
	01.62.29I	Tibial insert trial-Fixed-PS-SZ 11-26T	

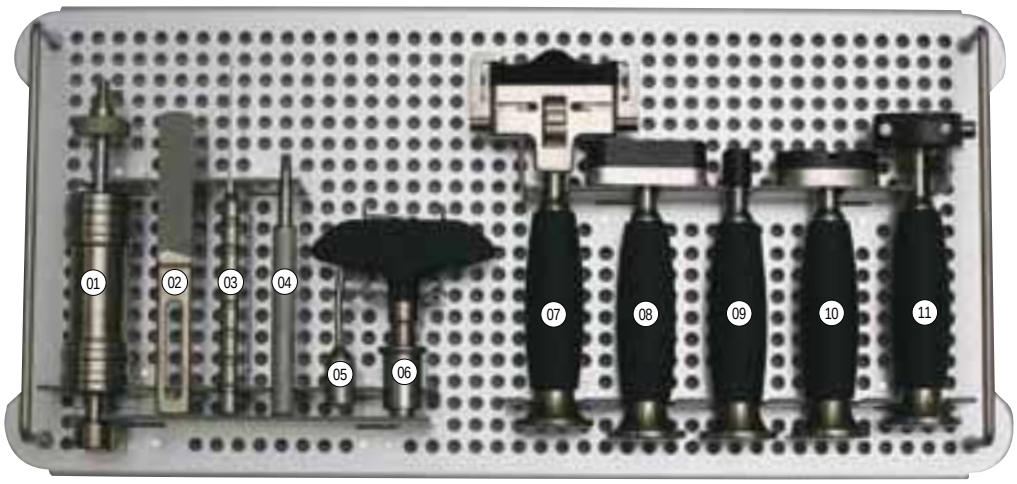
* : Flow production

Ⅷ. Instrument Ordering Information



Impactor Instrumentation Tray

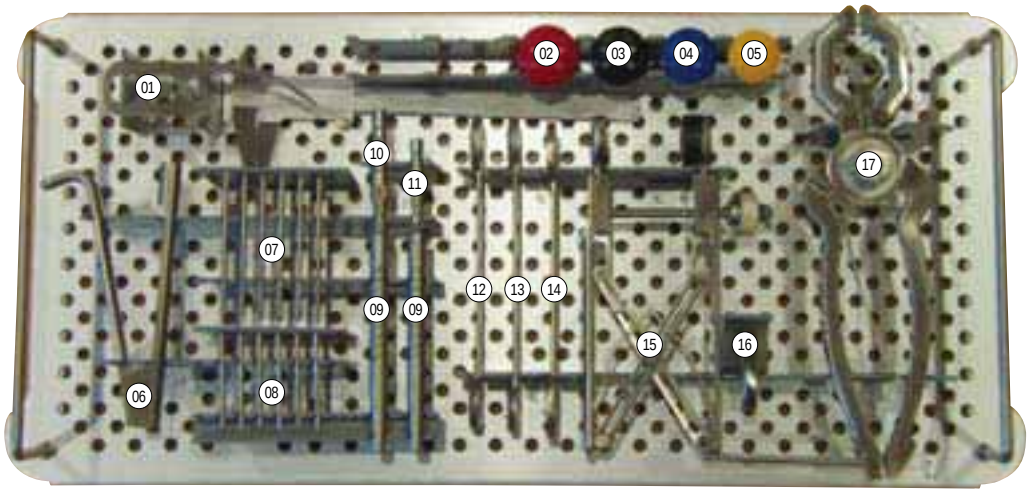
Label No.	Part No.	Description	Product
01	01.61.222	Slap hammer	
02	01.61.215	Bone file	
03	01.61.214	Chisel	
04	01.61.226	Hex driver	
05	01.61.223	Universal extractor	



Impactor Instrumentation Tray

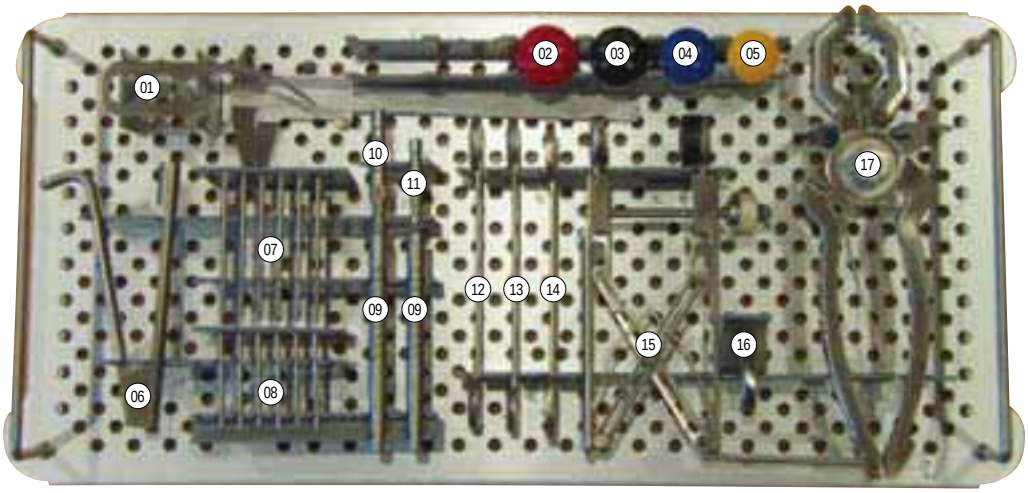
Label No.	Part No.	Description	Product
06	01.61.212	Modular T-handle	
07	01.61.151	Femoral Holder	
08	01.61.152	Femoral impactor	
09	01.61.189	Tibial insert impactor	
10	01.61.188	Tibial baseplate impactor	
11	01.61.187	Tibial baseplate Holder	

Ⅷ. Instrument Ordering Information

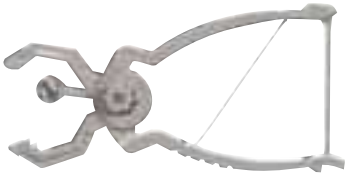


Patella Instrument Tray

Label No.	Part No.	Description	Product
01	01.61.125	Angel wing	
02	01.62.9A2	Patella trial-Dome type-Ø34x9mm	
03	01.62.981	Patella trial-Dome type-Ø32x8mm	
04	01.62.961	Patella trial-Dome type-Ø30x8mm	
05	01.62.941	Patella trial-Dome type-Ø28x8mm	
06	01.61.221	Pin extractor	
07	01.61.225	Baseplate headless	
08	01.61.225	Baseplate headed pin	
09	01.61.219	Pin impactor	



Patella Instrument Tray

Label No.	Part No.	Description	Product
10	01.61.220	Pin driver	
11	01.61.202	Patella peg drill	
12	01.61.203	Patella peg drill guide (26, 28)	
13	01.61.204	Patella peg drill guide (30, 32)	
14	01.61.205	Patella peg drill guide (34, 36)	
15	01.61.201	Patella clamp	
16	01.61.201-D7	Patella peg drill guide	
17	01.61.200	Patella resection guide	

IX. IFU for Lospa Knee System

DESCRIPTION

Corentec Co., Ltd. manufactures a variety of knee joint replacement prostheses intended for application with bone cement. Knee joint replacement components include femoral, tibial, and patellar components. Components are available in a variety of designs and size ranges intended for primary applications.

Materials :

LOSPA™ Femoral Component :
CoCrMo alloy (ISO 5832-2)
LOSPA™ Tibial Baseplate :
CoCrMo alloy (ISO 5832-2)
LOSPA™ Tibial Insert :
Ultra-High Molecular Weight Polyethylene (UHMWPE: ISO 5834-2)
LOSPA™ All-PE Tibial Component :
Ultra-High Molecular Weight Polyethylene (UHMWPE: ISO 5834-2)
LOSPA™ Patellar Component :
Ultra-High Molecular Weight Polyethylene (UHMWPE: ISO 5834-2)

INDICATIONS

1. This device is indicated for the treatment of diseases as follows :

- Painful, disabling joint disease of the knee resulting from non-inflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or rheumatoid arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture management techniques.

2. Patient selection factors to be considered include:

- Need to obtain pain relief and improve function
- Ability and willingness of the patient to follow instructions, including control of weight and activity level
- A good nutritional state of the patient
- The patient must have reached full skeletal maturity.

GENERAL CONDITION OF USE

1. Specialized instruments are designed for Corentec joint replacement systems to aid in the accurate implantation of the prosthetic components. The use of instruments or implant components from other systems can result in inaccurate fit, sizing, excessive wear and device failure. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Surgical instruments should only be used for their intended purpose. Corentec Co., Ltd. recommends that all instruments be regularly inspected for wear and disfigurement.
2. Radiographic templates are available to assist in the preoperative prediction of component size and style.
3. Use the recommended trial components for size determination, trial reduction and range of motion evaluation to preserve the integrity of the actual implants and their sterile packaging.
4. Do not reuse implant. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant.
5. Do not treat patients with implants that have been, even momentarily, placed in a different patient.
6. Care should be taken to remove bone chips, bone cement fragments and metallic debris from the implant site to reduce the risk of debris induced accelerated wear of the articular surface of the implant.
7. Consult the product label for specific product compatibility.

CONTRAINDICATIONS

1. Absolute contraindications include:

- Infection
- Sepsis
- Osteomyelitis

2. Relative contraindications include:

- Uncooperative patient or patient with neurologic disorders who are incapable of following directions
- Osteoporosis
- Metabolic disorders which may impair bone formation
- Osteomalacia
- Distant foci of infections which may spread to the implant site
- Rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram
- Vascular insufficiency, muscular atrophy, neuromuscular disease
- Incomplete or deficient soft tissue surrounding the knee.

ADVERSE EFFECTS

1. While the expected life of total knee replacement components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physiochemical factors which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone. Surgeons should counsel patients against having unrealistic expectations about the lifetime of the device.
2. Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process. Particulate wear debris and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate a cellular response resulting in osteolysis or ostelysis may be a result of loosening of the implant.
3. Early or late postoperative, infection, and allergic reaction.
4. Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device.
5. Loosening or migration of the implants can occur due to loss of fixation, trauma, malalignment, bone resorption, excessive activity. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis, component malalignment or trauma. Late loosening may result from trauma, infection, biological complications including osteolysis, or mechanical problems, with the subsequent possibility of bone erosion and/or pain.
6. Periarticular calcification or ossification, with or without impediment of joint mobility.
7. Inadequate range of motion due to improper selection or positioning of components.
8. Undesirable shortening of limb.
9. Dislocation and subluxation due to inadequate fixation and improper positioning. Muscle and fibrous tissue laxity can also contribute to these conditions.
10. Fatigue fracture of component can occur as a result of loss fixation, strenuous activity, malalignment, trauma, non-union, or excessive weight.
11. Fretting and crevice corrosion can occur at interfaces between components.
12. Wear and/or deformation of articulating surfaces.
13. Valgus-varus deformity.

14. Peripheral neuropathies, nerve damage, circulatory compromise and heterotopic bone formation may occur.
15. Transient peroneal nerve palsy secondary to surgical manipulation and increased joint movement has been reported following knee arthroplasty in patients with severe flexion and valgus deformity.
16. Venous thromboembolic disease.
17. Patellar tendon rupture and ligamentous laxity.
18. Interoperative or postoperative bone fracture and/or postoperative pain.

PRECAUTIONS

1. The patient must be advised of both the limitations of the reconstruction and the need for protection of the implant from full weight bearing until adequate fixation and healing have occurred. Excessive activity and trauma affecting the joint replacement have been implicated in failure of the reconstruction by loosening, fracture and/or wear of the prosthetic implants. Loosening of the components can result in increased production of wear particles, as well as damage to the bone, making successful revision surgery more difficult.
2. The patient should be cautioned to limit activities and protect the replaced joint from unreasonable stresses, and to follow the instructions of the physician with respect to follow-up care and treatment.
3. The patient should be warned of surgical risk, and made aware of possible adverse effects. The patient should be warned that the device does not replicate the flexibility, strength, reliability, or durability of a normal healthy joint, that the implant can break or become damaged as a result of strenuous activity or trauma, and that the device has a finite service life and may need to be replaced in the future.
4. Appropriate selection, placement and fixation of the total knee components are critical factors which affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanic and other extrinsic factors, which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions and warnings for this product is essential to potentially maximize service life.

WARNINGS

1. The surgeon is to be thoroughly familiar with the implants and instruments, prior to performing surgery.

- The All-PE tibial component is designed to be used in treatment of low demand, less active sedentary patients. Patients that will remain active and/or overweight patients are not candidates for All-PE tibial components.
- Malalignment or soft tissue imbalance can place inordinate forces on the components which may cause excessive wear to the patellar or tibial insert articulating surfaces. Revision surgery may be required to prevent component failure.
- Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentrations, which may lead to failure of the procedure. Implant fracture due to cement failure has been reported.
- Complete preclosure cleaning and removal of bone cement debris, metallic debris, and other surgical debris at the implant site is critical to minimize wear of the implant articular surfaces.

2. Improper selection, placement, positioning, alignment and fixation of the implant components may result in unusual stress conditions which may lead to subsequent reduction in the service life of the prosthetic components.

3. Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc) can lead to crevice corrosion, fretting, fatigue fracture and /or excessive wear.

- Do not use all damaged or mismatched implants
- Never reuse an implant, even though it may appear undamaged.
- Use clean surgical gloves when handling implants.
- Polished bearing area must not come in contact with hard or abrasive surfaces.
- Do not modify implants. Contouring or bending of an implant may reduce its fatigue strength and cause failure under load.
- Care should be taken not to cut through surgical gloves when handling any sharp-edged orthopaedic device.

4. Except where noted, Corentec Co., Ltd. strongly advises against the use of another manufacturer's total knee component with any Corentec total knee replacement. Any such use will negate the responsibility of Corentec Co., Ltd. for the performance of the resulting mixed component implant.

5. Intentional removal of total knee component can be accomplished by careful use of cutting burs, thin and narrow osteotomes and cautions extraction forces.

6. Intentional removal of the plastic tibial insert after its assembly into the metal tibial baseplate results in the destruction of the plastic insert. Care should be taken not to nick or notch the surface of the tibial baseplate during insert removal.

7. Corentec joint replacement prostheses provide the surgeon with a means of reducing pain and restoring function for many patients. While these devices are generally successful in attaining these goals they cannot be expected to withstand the activity levels and loads of normal healthy bone and joint tissue.

8. Accepted practices in postoperative care are important. Failure of the patient to follow postoperative care instructions involving rehabilitation can compromise the success of the procedure.

- The patient is to be advised of the limitations of the reconstruction and the need for protection of the implant from full load bearing until adequate fixation and healing have occurred.
- Excessive activity, trauma and excessive weight have been implicated with premature failure of the implant by loosening, fracture, and/or wear.
- The patient is to be made aware and warned of general surgical risks, possible adverse effects as listed, and to follow the instructions of the treating physician including follow-up visits.

PACKAGING, LABELING AND STORAGE

1. Components are delivered in sterilized packages. These must be intact at the time of receipt. All the legal information required for this type of implants is given on the label of each package.
2. Care should be taken to handle implants and instruments.
3. Implants and instruments should be stored in the place where protected from corrosive environments such as salt air, moisture, etc.

STERILITY

1. Prosthetic components are sterilized by exposure to a minimum dose of 25 kGy of gamma radiation.
2. Do not resterilize.
3. Do not use any component from an opened or damaged package.
4. Do not use implants after expiration date.

STORAGE AND DISPOSAL

1. Store at cool and clean environment without direct sunlight.
2. Used or fractured products should be returned to local representative or Corentec Co., Ltd to dispose safely.

GUARANTEE

The guarantee is only applicable if the device is used in accordance with normal conditions, as defined in this instruction.

IMPLANT SPECIALIST

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Seoul Office 11F Chungho Tower, 748-1 Banpo 1-dong, Seocho-gu, Seoul, Korea 137-040 | TEL 82-2-3445-5492~5 | FAX 82-2-3445-5497
Home page : www.corentec.com

Distributor

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